REMARKS

The amendments to the claims do not add new matter. Claim 111 has been amended to recite that the "assembled implant is "suitable for implantation into a patient." Support for the "assembled implant" being "suitable for implantation into a patient" is found throughout the specification, including at page 4 line 19 (". . .shipment to physicians for use in implantation procedures."). Claim 111 has also been amended to recite that the through holes are "circular." Support for the through holes being "circular" is shown in FIG. 7A as circular holes 701, 702, 703 and 704; and is found in the specification at page 19, line 4 ("holes 701-704 have been drilled"). Accordingly, the amendments to claim 111 would not add new matter.

New claims 129-136 parallel claims 111-118 with the exception that claim 129 recites that both cortical bone portions are "allograft" bone. Support for the bone being "allograft" is found in the specification at page 3, line 5.

For all these reasons, the amendments to the claims do not add new matter.

Summary of the Bases for Rejection/Objection

Claims 111-118 and 120-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over all claims in USSN 10/375,540.

Claims 111-118 and 120-123 are rejected under 35 U.S.C. § 102(b) over Albee, Scientific American, "Bone Surgery with Machine Tools," 154(4) 178-181 (1936).

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels).

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates).

The Applicants will answer each of these bases for objection in Sections I-IV, respectively which follow.

I. Obviousness-type Double Patenting

Claims 111-118 and 120-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over all claims in co-pending sister application USSN 10/375,540. No claims have been deemed allowable in the present application. Applicants will consider cofiling an appropriate terminal disclaimer at such time as claims are determined to be allowable.

II. 35 U.S.C. § 102(b) over Albee

Claims 111-118, 120-123 and 126-127 are rejected under 35 U.S.C. § 102(b) over Albee, Scientific American, "Bone Surgery with Machine Tools," 154(4) 178-181 (1936). In response to the Official Action of 12/15/04, the Applicants amended claim 111 to recite "An assembled bone implant suitable for implantation into a patient. . ." The Patent Office responded stating "Regarding the language 'suitable for implantation into a patient' found in the preamble, it is not clear if that **limitation** breathes any life and meaning into the claim." [Official Action at page 2; emphasis added in bold.] The Patent Office acknowledges that the words are a "limitation" but then misconstrues what is meant by "breathing life and meaning" into a claim. The test is whether the language in the preamble is merely a preambular statement of purpose, which is given no weight as a limitation, or is necessary to give life and meaning to the claim. The courts have recognized that when the body of a claim contains an express reference back to the antecedent recitation in the preamble, then that recitation is incorporated by reference into the claim. See Thus, in the body of claim 111, the reference back to "the assembled bone implant" means "the assembled bone implant suitable for implantation into a patient." However, at the cost of being redundant, the Applicants have amended the last phrase in the body of claim 111 to recite "said assembled bone implant being suitable for implantation into said patient." Accordingly, this recitation is now an element of claim 111.

Citing to "all figures, specifically figures 10-12 and 15," the Patent Office

states that Albee discloses the elements of claim 111, prior to the amendments herein. [Official Action at page 4.]

> a first cortical bone portion;
> a second cortical bone portion;
> said first cortical bone portion and said second cortical bone portion having one or more circular through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and
> one or more retention pins of appropriate diameter for fitting said through holes and connecting said first cortical bone portion to said second cortical bone portion ~~to form~~ and forming said assembled bone implant as a unitary body outside of said patient, said assembled bone implant being suitable for implantation into said patient.
>
> [Claim 111 as amended herein.]

The Applicants respectfully disagree.

Albee only has Figures 1-6. However, when the Patent Office is referring to FIGS. 10-12 and 15 of Albee, it is believed that the Patent Office is referring to the subparts in Figure 3 of Albee, which has subparts 1-15 therein. If the Applicants are wrong, then the Applicants request a corrected Official Action wherein the Figures are properly designated and the Applicants are not required to speculate.

1. Albee Does Not Disclose Implants That Exist in Assembled Form Outside the Body

As an initial matter, Applicants point out that the applicants are claiming an "assembled" implant that exists in "assembled" form outside the body (in vitro) and that is "suitable for implantation in the patient's body." They are "off the shelf" assembled devices (i.e., devices in the mechanical sense). In marked contrast, all of the grafts

disclosed in Figure 3 of Albee fail to exist in assembled form outside the body. There is no "assembled" implant disclosed in Albee that exists outside the body, and that in assembled form is "suitable for implantation into a patient." Rather, Albee discloses shaping a single piece of the patient's own (autograft) bone to fit between two opposing segments of the patient's living in vivo bone to bridge a size gap or hold the two opposing living segments in appropriate juxtaposition. The resulting assembled structure is not an "assembled implant" it is a reconstructed area. Moreover, whatever is assembled in a patient in Albee exists only in vivo, and is not "suitable for implantation in a patient" because it would require removing the patients' own bones and the interconnecting piece so that they exist in vitro as an assembled implant. Thus, at no time does Albee ever teach an "assembled implant" suitable for implantation in the body. Consistent with this interpretation, the Applicants have expanded the body of independent claim 111 to recite that the already "assembled implant" is "suitable for implantation in a patient."

Throughout Albee's disclosure, Albee discloses that the single piece of bone is removed from one portion of the patient as living tissue, is shaped and then transferred as a single (living) piece to the living bone in the body of the patient:

> The **graft lives** if it is supplied sufficiently early and in quantity with blood from the host.
>
> [Albee at page 180, col. 1; emphasis added in bold.]
>
> * * *
>
> The **vascular channel**, especially the **capillaries**, in the **graft** and host bone unite.
>
> [Albee at page 180, col. 3; emphasis added in bold.]
>
> * * *
>
> **Compression may kill bone cells**, either **in graft** or host tissues, or close blood vessels that should otherwise bring nourishment to the **living graft cells**.

[Albee at page 181, col.2; emphasis added in bold.]

* * *

> The successful **living bone-graft** is based upon a tripod of exacting conditions and environment as to mechanics, physiology and biology.
>
> [Albee at page 181, col.2; emphasis added in bold.]

Thus, at no time does Albee disclose an isolated "assembled implant" that is suitable for implantation in a patient. Further, drawing 7 in Figure 3 of Albee is the only drawing that discloses the use of more than one isolated piece of bone. It shows the use of two pieces of bone that would be connected in the living body sequentially and never as "an assembled implant."

Albee describes subparts 11 and 12 of Figure 3 as follows "Numbers 11 and 12 are keyed-in tension members in **broken knee caps** which **will not join**." [Albee at the caption to Figure 3; emphasis added in bold.] The broken knee caps of subparts 11 and 12 of Figure 3 are "**broken**" not disconnected from the respective tendons. They "**will not join**" because they are connected to their respective tendons which are pulling them in opposite directions. For simplicity, the tendons were not shown. However, as "broken" knee caps, they exist inside the body of the patient, connected by their respective tendons to the remainder of the body. At no time do they exist outside the body so as to satisfy the limitation to an assembled implant "forming a unitary body outside the patient suitable for implantation into the patient." For all these reasons, claims 111-118 and 120-123 would not be anticipated by Albee.

2. FIGS. 11 and 12 of Albee (Subparts 11 and 12 of Fig. 3) fail to show "D" shaped bone portions

Claim 112 recites that "said first cortical bone portion and said second cortical bone portion each have a D shape." Claims 114-115 and 117-118 incorporate this limitation by reference thereto. The Patent Office contends that in figures 11-12, "Albee

teaches superimposed cortical bone portions each having a **D-shape** having a through hole with [sic "which"] receives the I shaped pin interpreted as having the **appropriate diameter**." [Official Action at page 4.] The Applicants respectfully disagree.

One skilled in the art, and even a child, understands that the letter "D" is a closed loop. In contrast, the letter "C" is an open loop. The knee cap fragments shown in subparts 11 and 12 of Figure 3 of Albee are open loops and thus at best "C" shaped not "D" shaped. For this reason, claims 112, 114-115 and 117-118 would not be anticipated by Albee.

Separately, the I-shaped insert of subpart 11 of Albee and the X-shaped tenon insert of subpart 12 of Figure 3 of Albee do not have a "diameter." However, the Patent Office has "interpreted" the I-shape and the X-shape inserts of Albee as "having the appropriate diameter." [Official Action at page 4.] The Applicants request that the Patent Office point out where the "diameter" occurs, since a diameter is by definition associated only with circular or spherical objects.

> diameter- the straight line passing through the center of a **circle**, **sphere**, etc., from one side to the other.
>
> [Exhibit B: Webster's New World Dictionary, Second College Edition, Ed, Guralnik, Prentice Hall Press, Cleveland Ohio 1986 at page 389; emphasis added in bold.]

In contrast, the I-shaped and X-shaped inserts of subparts 11 and 12 of figure 3 are substantially planar and have straight line edges. For these reasons also, claims 111-118 and 120-123 would not be anticipated by Albee.

3. FIGS. 11 and 12 of Albee (Subparts 11 and 12 of Fig. 3) fail to show a through hole in the bone portions

The Patent Office next alleges that in figures 11 and 12, "Albee teaches superimposed first and second cortical bone portions each having a D-shape having a **through hole** with [sic "which"] receives the I shaped pin interpreted as having the appropriate diameter." [Official Action at page 4; emphasis added in bold.] One skilled in

the art, and even a child, knows that a "hole" by definition is surrounded by the material into which it is placed. For example, it is elementary that a donut hole is surrounded by the rest of the donut. If it looked as in subparts 11 or 12 of Albee, one skilled in the art would know that someone took a bite out of their donut. Likewise, a button hole on a shirt is surrounded by the rest of the shirt. If it looked like subparts 11 and 12 of Albee it would be a **notch** and not a **hole**, and it would cease to function. Finally, when a golfer hits a "hole in one" the "hole" is surrounded by the green. It is not a notch in the side of a hill. By comparison, a "notch" is defined as a cut or indentation in a surface:

> **notch** a concave or V-shaped **cut or indentation in an edge** or across a surface.
>
> [Exhibit B: Webster's New World Dictionary, Second College Edition, Ed, Guralnik, Prentice Hall Press, Cleveland Ohio 1986 at page 973; emphasis added in bold.]

Referring back to subparts 11 and 12 of Figure 3 of Albee, it is clear that the broken knee cap fragments have a "notch" in their adjoining **edges** and not a hole that is otherwise surrounded by kneecap. For this reason also, claims 111-118 and 120-123 would not be anticipated by Albee.

4. Half of the Items disclosed in Figure 3 of Albee are a cabinet maker's "joinery" which Albee presents for "analogy"

Addressing the merits of the rejection, in Figure 3 of Albee, each of subparts 1a, 2b, 3a, 4a, 5a, 6a, 7a, 7b, 8a, 9a, 10a 11a, 11b, 12a, 13a, and 15 are cabinetry joints (i.e., "joinery elements"), which Albee cites to as analogy, and not actual implants in a patient:

> The fine joinery element in bone surgery-a group of **self evident analogies**.
>
> [Albee at caption to Figure 3; emphasis added in bold.]
>
> * * *
>
> For help with the mechanical problem, **one must go to the joiner**

> and **study** his various forms of **mortise** and how he selects each according to the mechanical demands of the situation (Figure 3).
>
> [Albee at page 180, col. 2; emphasis added in bold.]

In Figure 3, only subparts 1, 2, 2a, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, and 14 show a bone repair using a single isolated and shaped piece of living bone to connect or bridge the gap between adjacent pieces of bone in vivo. As discussed above, subpart 7 of Figure 3 discloses the use of two separate pieces of bone that are connected (by the disclosed mortise and tenon joint) only when attached to the body (in vivo). Thus, at no time does Albee teach or suggest an "assembled implant suitable for implantation in a patient."

For all these reason, Albee would not be anticipatory of any of claims 111-118, (withdrawn claim 119), 120-123, and 126-127 of the present invention. Albee also would not be anticipatory of any of newly added claims 129-136 because they include the same limitations.

III. 35 U.S.C. § 103(a), Coates over Siebels

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels). According to the Patent Office, "[r]eferring to all figures, Coates teaches a D-shaped cortical bone spinal implant. . . ." [Official Action at pages 5 citing to Coates at col. 11, lines 42 et seq.] The Patent Office admits that "**Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin**." [Official Action at page 5; emphasis added in bold.] To make up for this deficiency, the Patent Office cites to Siebels, stating that Siebels discloses "a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17." [Official Action at page 4.] The Patent Office then concludes that "[i]t would have been obvious to one skilled in the art to have utilized the teachings of Siebels to stack and connect the individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably

build the implant to a desired height (thickness) to best fill the disk space as desired by the surgeon." [Official Action at page 5.] The Applicants respectfully disagree.

In order for an invention to be obvious, "Both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure." Amgen v. Chugai, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, Siebels discloses that it was an object of their invention to make an implant that can "easily be manufactured for a multiplicity of overall dimensions:"

> Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also **easily be manufactured** for a **multiplicity of overall dimensions**, forms the basis of the [proposed] invention.
>
> In accordance with the invention, the set objective is achieved with the help of the features, cited in claim 1.
>
> [English Translation of Siebels at page 2, line 20 to page 3, line 1; emphasis added in bold.]

To achieve the "ease" of manufacturing, Siebels relies upon cutting discs out of "prefabricated solid or hollow strand." [English Translation of Siebels at page 3, line 7.] Specifically, Siebels discloses that this mode of manufacturing, comprising cutting appropriately sized strands made of "fiber reinforced plastic" provides for "manufacturing" in a "extraordinarily easy way":

> The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity** and **strength** to

the implant.

[English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

Thus, the heart of Siebel's invention is a prefabricated template that can be cut into directly useable slices to produce an implant "in an extraordinarily easy way." By use of the adjective "extraordinary," Siebels meant to convey that the disclosed process of manufacturing plastic implants was not just "easy" but "extraordinarily easy."

In addition, the above quote from Siebels teaches that "fiber orientation" is important because it "imparts an optimal rigidity." The word "optimal" is a superlative and means "most favorable or desirable; best; optimum." [Exhibit B: Webster's New World Dictionary, Second College Edition, Ed. Guralnik, Prentice Hall Press, 1986 at page 999; emphasis added in bold.] Thus, fiber orientation is a necessary element in the material used by Siebels to "impart optimal rigidity."

In contrast to the "extraordinarily easy" method of manufacturing disclosed in Siebels (that provides for an implant having "optimal rigidity"), Coates discloses that "developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been extremely difficult or impossible." [Coates at col. 3, lines 35-39.] By this statement, Coates teaches that as of its filing date (October 1995), cortical bone was not a "traditional orthopedic implant material" for spinal implants. It was considered "extremely difficult or impossible" to provide an implant that had the benefits of both bone and metal without their undesired properties. The words "extremely difficult or impossible" are superlatives related to difficulty or impossibility. Given this "extremely difficult or impossible" setting, one would not have been motivated to substitute the cortical bone of Coates for the preformed plastic of Siebels. Given the art recognized extreme difficulty or impossibility, one skilled in the art would have even been less motivated to build an implant from little pieces of bone held together with pins, and there would not have been a reasonable expectation of success that the Applicants' would have been able to make implants for use in the spine from assembled pieces of cortical bone. See Amgen v. Chugai, 18 USPQ2d at 1022. For

these reasons, claims 111-118 and 120-128 would not have been obvious under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates).

In response to the Applicants' arguments, the Patent Office contends that "Coates specifically states that the implant of Brantigan is flawed because the materials used (including metals) of Brantigan are too stiff which causes stress shielding, etc." [Official Action at page 3.] However, as correctly pointed out in the very next sentence of the Official Action, Coates remarks are limited to metals:

> Coates in the very next paragraph teaches that bone as an implant material "**avoid[s] the disadvantages of metal implants**": see column 2, lines 49 et seq.
>
> [Official Action at page 3, quoting Coates; emphasis added in bold.]

However, Siebels' implants are not limited to metals. Siebel also teaches that its **preferred embodiment** is not a metal either, but rather is a fiber (e.g., graphite) reinforced plastic (as on the stealth bomber), which does not have the disadvantages associated with metal such as stress-shielding, or radio-opaqueness:

> The disk-shaped implant is **preferably** made of **fiber-reinforced plastic [FRP]**. In accordance with a **preferred embodiment** of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity** and **strength** to the implant.
>
> [English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

See also Brantigan at [Brantigan at col. 3, lines 9-12 ("The **implants** are **preferably** made

of **radiolucent** material such as **carbon fiber reinforced polymers**. . . .").] Coates does not address or overcome the advantages associated with fiber reinforced plastic, so as to motivate one skilled in the art to disregard the advantages associated with Siebels' ease of construction and stated advantages relative to bone which required complex machining and was totally untested in stacked formation. In fact, Siebels states that this preferred embodiment imparts "**optimal rigidity**." Coates never addressed this preferred embodiment which Siebels also disclosed was "preferred" over metal.

For this reason and all of the above reasons, the combination of Coates and Siebels would have failed to render obvious claims 111-118 and 120-128 at the time that the Applicants' invention was made.

IV. 35 U.S.C. § 103(a), Brantigan over Coates

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates). According to the Patent Office, Figures 2 and 5 of Brantigan teach a D-shaped implant comprising:

> a first portion 21;
>
> a second portion 21;
>
> said first portion and said second portion having one or more through holes 24 sized and positioned for receiving one or more retention pins 15 for connecting said first ~~cortical bone~~ [sic] portion to said second ~~cortical bone~~ [sic] portion; and
>
> one or more retention pins of appropriate diameter for connecting said first ~~cortical bone~~ [sic] portion to said second ~~cortical bone~~ [sic] portion to form said assembled bone implant unitary body.
>
> [Official Action at pages 6-7; strikeout corrections added.]

The above statement from the Patent Office is incorrect on its face because Brantigan never discloses any component or "portion" of an implant that is made of "**cortical bone**." In a

later sentence of the Official Action, the Patent Office acknowledges that "**Brantigan fails to teach that the first and second portions are cortical bone.**" [Official Action at page 7; emphasis added in bold.] Moreover, in the Patent Office's argument quoted above, the terms "said first cortical bone portion" and "said second cortical bone portion" lack antecedent basis and the resulting argument is indefinite. As a result, it is difficult to know what the Patent Office is contending.

1. When Brantigan is Properly interpreted, there is no Motivation to substitute the cortical bone of Coates for the "fiber reinforced plastic" in the implants of Brantigan

The Patent Office next contends that "[i]t would have been obvious to one of ordinary skill in the art to have used cortical bone which is a traditional, orthopaedic implant material as taught by Coates for any of the elements of Brantigan because '5,192,327 to Brantigan teach hollow metal cage structures. Unfortunately, due to the stiffness of the material, some metal implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. Metal devices are also foreign bodies which can never be fully incorporated into the fusion mass.'" [Official Action at page 7.] The Applicants respectfully submit that Coates misinterprets Brantigan.

Specifically, Coates teaches away from the use of metals, just as Brantigan teaches away from metals. As a matter of law, "A prior art reference may be considered to **teach away** when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant**." *Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998) (emphasis added in bold.). In particular, Brantigan teaches that fiber reinforced plastics are "preferred" over metals:

> The **implants** are **preferably** made of radiolucent material such as **carbon fiber reinforced polymers** known commercially as

> "Peek", (polyetherether ketone) or "Ultrapek" (polyether ketone, ether ketone, ketone). Alternately, polycarbonate, polypropylene, polyethylene and polysulfone type plastics material filled with glass or carbon fibers can be used. Such materials are supplied by ICI Industries of Wilmington, Del.; Fiber-Rite Corporation of Winona, Minn. or BASF Corporation.
>
> [Brantigan at col. 3, lines 9-18; emphasis added in bold.]

In fact, other than in Brantigan's Abstract, Brantigan never mentions the five specific metals (that are the traditional orthopaedic materials). Thus, Brantigan taught away from the use of metals by teaching that a preference for fiber reinforced plastic (as also used in Siebels), over metals. Coates never addressed Brantigan's primary disclosure, which is directed to the use of fiber reinforced plastics which is the heart of Brantigan's invention. Further, Coates' arguments at col. 2, lines 54-65 regarding the stress shielding caused by the stiffness of titanium alloys (114Gpa) and 316L stainless steel (193Gpa) versus cortical bone (about 17Gpa) do not apply to the carbon fiber reinforced PEEK (17.8 Gpa), carbon fiber reinforced polyetherketoneetherketoneketone (PEKEKEKK) (6.9-29.4 Gpa) or carbon fiber reinforced polycarbonate (4.1-21.4 Gpa) as disclosed in Brantigan at col. 3, lines 9-13. [See Exhibit A: from www.matweb.com at page 2, line 10 "Flexural modulus".] These fiber reinforced polymers have a stiffness (e.g. 17.8 Gpa) that is analogous to the stiffness cortical bone (about 17 Gpa) and substantially less than the stiffness (114-193 Gpa) of the recited metals. [These arguments apply with equal force regarding the carbon fiber reinforced plastic of Siebels in Section III supra.] Thus, the fiber reinforced plastics of Brantigan do not have the disadvantage of "stress shielding" that is associated with metals. Further, the fiber reinforced plastics of Brantigan (and Siebel) offer yet another advantage of cortical bone because, unlike metals, both are transparent to X-rays. (See Coates at col. 2, lines 62-65 ("Moreover, bone as an implant also allows excellent postoperative imaging because it does not cause scattering like metallic implants on CT or MRI imaging."); Brantigan at col. 3, lines 9-10 ("The implants are preferably made of radiolucent material such as carbon fiber reinforced polymers known commercially as 'Peek' (polyetheretherketone) or 'ultrapeek' (polyether ketone, ether ketone, ketone)"); and Siebel

– Eng translation at page 6, 2nd full ¶ ("Preferably, the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means - according to the design of the implant - can consist of the same, or another material. The manufacturing of the entire implant of CFP has the advantage that the implant does not bring about any scattering of rays, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of all image-producing methods (CT, MR);" emphasis added in bold). Thus, Coates misstates the teaching in Brantigan, which is not limited to metal implants, but rather is directed as its preferred embodiment to implants made from "carbon fiber reinforced plastic." Hence, one skilled in the art, upon reading both Coates and Brantigan, would not have been motivated to substitute the cortical bone of Coates for the fiber reinforced plastic of Brantigan, which Coates never discussed.

2. There is No Suggestion to Substitute Cortical Bone for Plastic or a Reasonable Expectation of Success

The Patent Office next contends that it "would have been obvious to one having ordinary skill in the art to have utilized cortical bone which is a traditional orthopedic implant material as taught by Coates for any of the elements of Brantigan." [Official Action at page 7.] The Applicants respectfully disagree.

In order for an invention to be obvious, "Both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure." *Amgen v. Chugai*, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, at the time of Brantigan's 1991 filing date, Brantigan expressly teaches that the traditional orthopedic materials for spinal implants were "nickel, chromium, cobalt, stainless steel or titanium." [Brantigan at the Abstract, last two lines.] At the time of Coates' earliest claimed filing date (October 1995), Coates teaches that "developing an implant **having the biomechanical properties of metal** and the **biological properties of bone without the disadvantages of either** has been **extremely difficult or impossible**." [Coates at col. 3, lines 35-39; emphasis added in bold.] Thus, at the filing date (October

1995) of Coates, Coates teaches that cortical bone was not a "traditional orthopedic implant material" for spinal implants. It was considered "extremely difficult or impossible" to provide an implant that had the benefits of both bone and metal without their undesired properties. Given this "extremely difficult or impossible" setting, there would not have been a reasonable expectation of success that the Applicants' would have been able to make implants for use in the spine from assembled pieces of cortical bone. However, Coates comments, while specifically addressing metal implants, never addressed the graphite reinforced implants of Brantigan which even Brantigan preferred over metal and which had the same modulus of flexibility as bone (thereby overcoming stress shielding of metal) and which were radiolucent (thereby overcoming the radio-opacity of metal) and which were easy to make in any size. For these reasons, claims 111-118 and 120-128 would not have been obvious under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels)..

3. Even if Combined, the Combination of Coates and Brantigan would not make a prima facie case of Obviousness

Independent claim 111 of the Applicants' invention includes as elements the following:

> a first cortical bone portion;
>
> a second cortical bone portion;
>
> said first cortical bone portion and said second cortical bone portion having one or more **circular through holes** sized and positioned for receiving one or more **retention pins** for connecting said first cortical bone portion to said second cortical bone portion; and
>
> one or more **retention pins of appropriate diameter** for fitting said through holes and connecting said first cortical bone portion to said second cortical bone portion ~~to form~~ and forming said assembled bone implant as a unitary body outside of said patient, said assembled bone implant being suitable for implantation into

said patient.

[Claim 111 as amended herein; emphasis added in bold.]

Thus, one of the elements of Applicant's claim 111 is a "retention pin of appropriate diameter." Independent claim 120 also recites the same term "retention pin". One skilled in the art recognizes that the ordinary meaning of the term "diameter" means that the retention pin has a substantially circular cross section. This is also seen in the circular "through holes" 701-704 of Applicants' FIG. 7A. In contrast, Brantigan does not teach or suggest the use of any "pins" of any "diameter." Rather, Brantigan discloses the use of a "rectangular connecting bar" of FIG. 3 to interconnect a plurality of D-shaped plastic devices of FIG. 2 in stacked array as shown in FIG. 5 of Brantigan:

> These grooves are provided for mounting a rectangular connecting bar 15 shown in FIG. 3. This **bar** 15 has **flat side faces** 15a, rounded side edges 15b to **snugly fit the grooves** 14. . . .
>
> [Brantigan at col. 4, lines 25-28; emphasis added in bold.]

The Patent Office has acknowledged that Coates "fails to teach said implant can comprise a first and second portion capable of being connected by a pin." [Official Action at page 4.] Thus, the combination of Coates and Brantigan fail to teach or suggest an essential element of claim 111, i.e., a "retention pin" having a rounded cross section of "appropriate diameter" for the "**circular** through hole." Likewise independent claim 126 also recites as an element a "retention pin." Claims 112-118, 120-125 and 127-128, which ultimately depend from claims 111 and 126, would also incorporate the limitation to a "retention pin" and "circular through hole" by reference thereto. Accordingly, claims 111-118 and 120-128 would not have been obvious over the combination of Coates and Brantigan.

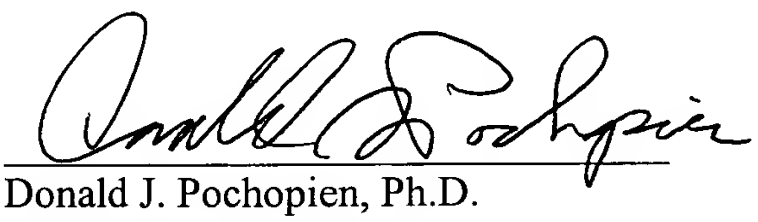
CONCLUSION

The provisional rejection of all claims of this restricted invention for double patenting over all claims of a separately restricted sister application will be address at such time as claims in one of the applications has been allowed. The rejection of claim 117 under 35 U.S.C. § 112, second paragraph, for indefiniteness has been rendered moot by amendment herein. The rejection of claims 111-118, 120-123 and 126-127 under 35 U.S.C. § 102(b) over Albee have been rebutted by evidence and arguments herein. The rejection of claims 111-118 and 120-128 under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels) have been rebutted by evidence and arguments herein. Finally, the rejection of claims 111-118 and 120-128 under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates) have been rebutted by evidence and arguments herein. For the same reasons, these bases for rejection should not apply to parallel claims 129-136 which include the same elements.

The allowance of claims 111-118 and 120-136 is respectfully requested.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: 

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Dated: December 19, 2005

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		SGL Carbon Group 30% SIGRAFIL C® - filled PEEK	Overview - Polyetherketoneetherketoneketone (PEKEKK), Carbon Fiber Filled	Overview - Polycarbonate, Carbon Fiber Reinforced
Physical				
1	Density (g/cc)	1.4	1.33 - 1.41	1.21 - 1.39
2	Water Absorption (%)	0.17	0.1 - 0.2	0.08 - 0.2
3	Linear Mold Shrinkage (cm/cm)	--	0.0005 - 0.001	0.0005 - 0.0053
4	Linear Mold Shrinkage, Transverse (cm/cm)	--	0.015	--
Mechanical				
5	Hardness, Rockwell R	--	--	118 - 120
6	Tensile Strength, Ultimate (MPa)	218	183 - 269	83 - 200

7	Tensile Strength, Yield (MPa)	--	--	110
8	Elongation at Break (%)	1.6	1.4 - 2.5	1.5 - 8
9	Modulus of Elasticity (GPa)	--	12.4 - 26.2	4.8 - 24.1
10	Flexural Modulus (GPa)	17.8	6.9 - 21.4	4.1 - 21.4
11	Flexural Yield Strength (MPa)	297	270 - 379	124 - 296
12	Compressive Yield Strength (MPa)	--	--	114 - 152
13	Izod Impact, Notched (J/cm)	--	1 - 1.1	0.48 - 1.87
14	Izod Impact, Notched (ISO) (kJ/m²)	9	--	--
15	Izod Impact, Unnotched (J/cm)	--	8 - 9.1	2.94 - 9.5
16	Izod Impact, Unnotched (ISO) (kJ/m²)	43.2	--	--
17	K (wear) Factor	--	5000	--
Electrical				
18	Electrical Resistivity (ohm-cm)	5500	100000	5 - 1e+010
19	Surface Resistance (ohm)	--	--	5 - 1e+010
Thermal				
20	CTE, linear 20°C (µm/m-°C)	--	--	13 - 31
21	Thermal Conductivity (W/m-K)	--	--	0.55 - 0.72
22	Maximum Service Temperature, Air (°C)	--	--	100 - 149
23	Deflection Temperature at 0.46 MPa (66 psi) (°C)	--	--	141 - 151
24	Deflection Temperature at 1.8 MPa (264 psi) (°C)	--	271 - 354	100 - 149

25	Glass Temperature (°C)	--	--	150
26	Flammability, UL94	--	V-0	HB - V-0
Processing				
27	Processing Temperature (°C)	--	--	300 - 318
28	Mold Temperature (°C)	--	--	85 - 121
29	Drying Temperature (°C)	--	--	120
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SECOND COLLEGE EDITION

WEBSTER'S NEW WORLD DICTIONARY

OF THE AMERICAN LANGUAGE

DAVID B. GURALNIK, *Editor in Chief*

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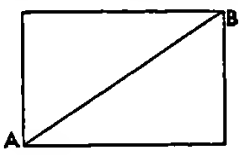
di·ag·o·nal (dī ag′ə n'l) *adj.* [L. *diagonalis* < Gr. *diagōnios* < *dia-*, through + *gōnia*, an angle, corner: for IE. base see KNEE] 1. extending between the vertices of any two nonadjacent angles in a polygonal figure or between any two vertices not in the same face in a polyhedral figure; extending slantingly between opposite corners 2. moving or extending obliquely, esp. at a 45° angle; slanting 3. having slanting markings, lines, etc. —*n.* 1. *a)* a diagonal line or plane *b) same as* VIRGULE 2. any diagonal course, row, order, or part 3. cloth woven with diagonal lines; twill —**di·ag′o·nal·ly** *adv.*



DIAGONAL

di·a·gram (dī′ə gram′) *n.* [Gr. *diagramma* < *diagraphein*, to mark out by lines, draw < *dia-*, through, across + *graphein*, to write: see GRAPHIC] 1. a geometrical figure, often used to illustrate a theorem 2. a sketch, drawing, or plan that explains a thing by outlining its parts and their relationships, workings, etc. 3. a chart or graph explaining or illustrating ideas, statistics, etc. —*vt.* **-gramed′** or **-grammed′**, **-gram′ing** or **-gram′ming** to show or represent by a diagram; make a diagram of —**di′a·gram·mat′ic** (-grə mat′ik), **di′a·gram·mat′i·cal** *adj.* —**di′a·gram·mat′i·cal·ly** *adv.*

di·a·ki·ne·sis (dī′ə ki nē′sis) *n.* [ModL. < DIA- + Gr. *kinēsis*, motion: see KINEMATICS] in the meiosis of germ cells, a stage in which the maternal and paternal chromosomes have paired within the nucleus —**di′a·ki·net′ic** (-net′ik) *adj.*

di·al (dī′əl, dīl) *n.* [ME. < ML. *dialis*, daily < L. *dies*, day: see DEITY] 1. a sundial 2. the face of a watch or clock 3. the face of a meter, gauge, compass, etc. on which a pointer or the like indicates an amount, degree, direction, etc. 4. a graduated disk on a radio, or television set, esp. one for tuning in stations or channels ☆5. a rotating disk on a telephone, used in making connections automatically —*vt.*, *vi.* **-aled** or **-alled**, **-al·ing** or **-al·ling** 1. to measure with or as with a dial 2. to show on a dial 3. to tune in (a radio station, television channel, program, etc.) ☆4. to call on a telephone by using a dial

dial. 1. dialect(al) 2. dialectic(al)

di·a·lect (dī′ə lekt′) *n.* [L. *dialectus* < Gr. *dialektos*, discourse, discussion, dialect < *dialegesthai*, to discourse, talk < *dia-*, between + *legein*, to choose, talk: see LOGIC] 1. the sum total of local characteristics of speech 2. the sum total of an individual's characteristics of speech; idiolect 3. any form of speech considered as deviating from a real or imaginary standard speech 4. the form or variety of a spoken language peculiar to a region, community, social group, occupational group, etc.: in this sense, *dialects* are regarded as being, to some degree, mutually intelligible while *languages* are not mutually intelligible 5. any language as a member of a group or family of languages [English is a West Germanic *dialect*] —*adj.* of or in dialect [*dialect* ballads] —**di′a·lec′tal** *adj.* —**di′a·lec′tal·ly** *adv.*

SYN.—**dialect**, in this comparison, refers to a form of a language peculiar to a locality or group and differing from the standard language in matters of pronunciation, syntax, etc.; **vernacular** today commonly refers to the informal or colloquial variety of a language as distinguished from the formal or literary variety; **cant**, in this connection, refers to the distinctive stock words and phrases used by a particular sect, class, etc. [clergymen's *cant*]; **jargon** is used of the special vocabulary and idioms of a particular class, occupational group, etc., esp. by one who is unfamiliar with these; **argot** refers esp. to the secret jargon of thieves and tramps; **lingo** is a humorous or mildly contemptuous term applied to any language, dialect, or jargon by one to whom it is unintelligible

dialect atlas *same as* LINGUISTIC ATLAS

dialect geography *same as* LINGUISTIC GEOGRAPHY

di·a·lec·tic (dī′ə lek′tik) *n.* [ME. *dialetik* < OFr. *dialetique* < L. *dialectica* (*ars*) < Gr. *dialektikē* (*technē*), the dialectic (art) < *dialektikos:* see DIALECT] 1. [*often pl.*] the art or practice of examining opinions or ideas logically, often by the method of question and answer, so as to determine their validity 2. logical argumentation 3. [*often pl.*] *a*) the method of logic used by Hegel and adapted by Marx to observable social and economic processes: it is based on the principle that an idea or event (*thesis*) generates its opposite (*antithesis*) leading to a reconciliation of opposites (*synthesis*) *b*) the general application of this principle in analysis, criticism, exposition, etc. —*adj. same as* DIALECTICAL

di·a·lec·ti·cal (-ti k'l) *adj.* 1. of or using dialectic or dialectics 2. of or characteristic of a dialect; dialectal —**di′a·lec′ti·cal·ly** *adv.*

dialectical materialism the philosophy stemming from Marx and Engels which applies Hegel's dialectical method to observable social processes and to nature

di·a·lec·ti·cian (dī′ə lek tish′ən) *n.* [Fr. *dialecticien*] 1. an expert in dialectic; logician 2. a specialist in dialects

di·a·lec·tol·o·gy (-täl′ə jē) *n.* the scientific study of dialects —**di′a·lec·tol′o·gist** *n.* —**di′a·lec′to·log′i·cal** (-tə läj′i k'l) *adj.* —**di′a·lec′to·log′i·cal·ly** *adv.*

di·al·lage (dī′ə lij) *n.* [Fr. < Gr. *diallagē*, change, interchange < *diallassein*, to interchange < *dia*, through + *allassein*, to alter < *allos*, other (see ELSE): so named from having unlike fracture planes] a dark-green mineral that is a laminated variety of pyroxene

di·a·log (dī′ə lôg′, -läg′) *n., v. same as* DIALOGUE

di·a·log·i·cal (dī′ə läj′i k'l) *adj.* of or marked by dialogue: also **di′a·log′ic** —**di′a·log′i·cal·ly** *adv.*

di·al·o·gist (dī al′ə jist, dī′ə lôg′ist, -läg′-) *n.* 1. a writer of dialogue 2. a person who takes part in a dialogue —**di·al·o·gis·tic** (dī′ə lô jis′tik) *adj.*

di·a·logue (dī′ə lôg′, -läg′) *n.* [ME. *dialog* < OFr. *dialogue* < L. *dialogus* < Gr. *dialogos* < *dialegesthai:* see DIALECT] 1. a talking together; conversation 2. interchange and discussion of ideas, esp. when open and frank, as in seeking mutual understanding or harmony 3. a written work in the form of a conversation 4. the passages of talk in a play, story, radio act, etc. —*vi.* **-logued′**, **-logu′ing** to hold a conversation —*vt.* to express in dialogue

Dialogue Mass *R.C.Ch.* a Low Mass at which the congregation, following an earlier custom now revived, makes the responses aloud and in unison

☆**dial tone** a low buzzing sound indicating to the user of a dial telephone that the line is open and a number may be dialed

di·al·y·sis (dī al′ə sis) *n., pl.* **-ses′** (-sēz′) [L. < Gr., separation, dissolution < *dialyein*, to separate, dissolve < *dia-*, apart + *lyein*, LOOSE] the separation of crystalloids or dissolved substances from colloids in solution by the greater diffusibility of the smaller molecules through a semipermeable membrane: used as in the mechanical elimination of impurities from the blood during kidney failure —**di·a·lyt·ic** (dī′ə lit′ik) *adj.* —**di′a·lyt′i·cal·ly** *adv.*

di·a·lyze (dī′ə līz′) *vt.* **-lyzed′**, **-lyz′ing** to apply dialysis to or separate by dialysis —*vi.* to undergo dialysis

di·a·lyz·er (-lī′zər) *n.* an apparatus for dialyzing, esp. one used as an artificial kidney

diam. diameter

di·a·mag·net·ic (dī′ə mag net′ik) *adj.* having or relating to diamagnetism —*n.* a diamagnetic substance, as bismuth or zinc: also **di′a·mag′net**

di·a·mag·net·ism (-mag′nə tiz′m) *n.* 1. the property that certain substances have of being repelled by both poles of a magnet and hence taking a position at right angles to the magnet's line of influence 2. diamagnetic force 3. diamagnetic phenomena 4. the science that deals with such phenomena and substances

di·a·man·té (dē′ə män tā′, -män′tā; *Fr.* dyä män tā′) *adj.* [Fr. < pp. of *diamanter*, to tinsel, lit., set with diamonds < *diamant*, DIAMOND] decorated with rhinestones or with other brightly glittering bits of material [*diamanté* sandals] —*n.* glittering ornamentation

di·am·e·ter (dī am′ət ər) *n.* [ME. & OFr. *diametre* < ML. *diametra* < L. *diametrus* < Gr. *diametros* < *dia-*, through + *metron*, a measure: see METER¹] 1. a straight line passing through the center of a circle, sphere, etc. from one side to the other 2. the length of such a line; width or thickness of a circular, or somewhat circular, figure or object 3. *Optics* the unit of measure of the magnifying power of a lens

di·a·met·ri·cal (dī′ə met′ri k'l) *adj.* 1. of or along a diameter: also **di·am·e·tral** (dī am′ə trəl) 2. designating an opposite, a contrary, a difference, etc. that is wholly so; complete [*diametrical* opposites]: also **di′a·met′ric** —**di′a·met′ri·cal·ly** *adv.*

di·am·ine (dī am′ēn, -in; dī′ə mēn′) *n.* any of a group of chemical compounds containing two NH_2 radicals; double amine

di·a·mond (dī′mənd, -ə mənd) *n.* [ME. *diamaunt* < OFr. *diamant* < ML. *diamas* (gen. *diamantis*), for L. *adamas* < Gr. *adamas*, adamant, diamond] 1. a mineral consisting of nearly pure carbon in crystalline form, usually colorless, the hardest natural substance known: transparent, unflawed stones are cut into precious gems of great brilliance; less perfect forms are used for cutting tools, abrasives, phonograph-needle tips, etc. 2. a gem or other piece cut from this mineral 3. *a*) a lozenge-shaped plane figure (◊) *b*) a red mark like this, used for one of the four suits of playing cards *c*) [*pl.*] this suit *d*) a card of this suit ☆4. *Baseball a*) the infield *b*) the whole playing field —*adj.* of, like, or set with a diamond or diamonds —*vt.* to adorn with or as with diamonds —**diamond in the rough** 1. a diamond in its natural state 2. a person or thing of fine quality but lacking polish

diamond anniversary the sixtieth, or sometimes seventy-fifth, anniversary of an event

di·a·mond·back (-bak′) *adj.* having diamond-shaped markings on the back —*n.* ☆1. a large, poisonous rattlesnake (*Crotalus adamanteus*) with diamond-shaped markings on its back, native to the S U.S. ☆2. an edible turtle (*Malaclemys terrapin*) with diamond-shaped markings on its shell, found in coastal salt marshes from Cape Cod to Mexico: in full, **diamondback terrapin** 3. a small, brown and white cosmopolitan moth (*Plutella maculipennis*) whose wings, when folded, form a diamond

Diamond Head promontory in Honolulu, Hawaii

optic axis in a crystal not having the same properties in all directions with regard to light, a direction along which there is no apparent double refraction since both components of the light ray have the same velocity
optic disk *same as* BLIND SPOT (sense 1)
op·ti·cian (äp tish′ən) *n.* [Fr. *opticien*] a person who makes or deals in optical instruments, esp. one who prepares and dispenses eyeglasses
optic nerve either of the second pair of cranial nerves, which connect the retina of the eye with the brain
op·tics (äp′tiks) *n.pl.* [*with sing. v.*] [< OPTIC] the branch of physics dealing with the nature and properties of light and vision
op·ti·mal (äp′tə məl) *adj.* [OPTIM(UM) + -AL] most favorable or desirable; best; optimum —**op′ti·mal·ly** *adv.*
op·ti·mism (-miz′m) *n.* [Fr. *optimisme* < L. *optimus*, best (see OPTIMUM)] 1. *Philos.* *a*) the doctrine held by Leibniz and others that the existing world is the best possible *b*) the doctrine or belief that good ultimately prevails over evil 2. the tendency to take the most hopeful or cheerful view of matters or to expect the best outcome; practice of looking on the bright side of things —**op′ti·mist** (-mist) *n.* —**op′ti·mis′tic** (-mis′tik), **op′ti·mis′ti·cal** *adj.* —**op′ti·mis′ti·cal·ly** *adv.*
op·ti·mize (-miz′) *vi.* **-mized′**, **-miz′ing** to be given to optimism —*vt.* to make the most of; develop or realize to the utmost extent; obtain the most efficient or optimum use of —**op′ti·mi·za′tion** *n.*
op·ti·mum (-məm) *n.*, *pl.* **-mums**, **-ma** (-mə) [L., neut. of *optimus*, best < *ops*, power, riches: for base see OPUS] 1. the best or most favorable degree, condition, amount, etc. 2. *Biol.* the amount of heat, light, moisture, food, etc. most favorable for growth and reproduction —*adj.* most favorable or desirable; best; optimal
op·tion (äp′shən) *n.* [Fr. < L. *optio* < *optare*, to wish, desire, ult. < IE. base **op-*, to choose, prefer] 1. the act of choosing: choice 2. the power, right, or liberty of choosing 3. something that is or can be chosen; choice 4. the right, acquired for a consideration, to buy, sell, or lease something at a fixed price, sign or renew a contract, etc. within a specified time —☆*vt. Sports* to transfer (a player) to a minor league with the option of recalling him —*SYN.* see CHOICE
op·tion·al (-′l) *adj.* left to one's option, or choice; not compulsory; elective —**op′tion·al·ly** *adv.*
op·to·e·lec·tron·ics (äp′tō i lek′trän′iks) *n.pl.* a branch of electronics involving the use of optical technology —**op′to·e·lec′tron′ic** *adj.*
op·tom·e·ter (äp täm′ə tər) *n.* [see OPTIC & -METER] an instrument for determining error in the refractive power of the eye
☆**op·tom·e·trist** (-trist) *n.* a specialist in optometry
op·tom·e·try (-trē) *n.* [see OPTIC & -METRY] 1. measurement of the range and power of vision 2. the profession of examining the eyes and measuring errors in refraction and of prescribing glasses to correct these defects —**op·to·met·ric** (äp′tə met′rik), **op′to·met′ri·cal** *adj.*
op·u·lent (äp′yə lənt) *adj.* [L. *opulentus* or *opulens* < *ops*: see OPUS] 1. very wealthy or rich 2. characterized by abundance or profusion; luxuriant —*SYN.* see RICH —**op′u·lence**, **op′u·len·cy** *n.* —**op′u·lent·ly** *adv.*
o·pun·ti·a (ō pun′shē ə, -shə) *n.* [ModL. < L. (*herba*) *Opuntia*, (plant) of Opus, city in Locris, Greece] any of a large genus (*Opuntia*) of cactus plants with red, purple, or yellow flowers, pulpy or dry berries, and fleshy, jointed stems, including the prickly pears and chollas
o·pus (ō′pəs) *n.*, *pl.* **o·pe·ra** (ō′pə rə, äp′ər ə), **o′pus·es** [L., a work < IE. **ops* < base **op-*, to work, riches, whence L. *ops*, riches, Sans. *ápas-*, work, OE. *efnan*, to work, do] a work; composition; esp., any of the musical works of a composer numbered in order of composition or publication
o·pus·cule (ō pus′kyōōl) *n.* [Fr. < L. *opusculum*, dim. of *opus*: see prec.] a minor work —**o·pus′cu·lar** *adj.*
-o·py (ō′pē) *same as* -OPIA
☆**o·quas·sa** (ō kwas′ə) *n.* [< *Oquassa* Lake, in Maine] a small trout (*Salvelinus oquassa*) of lakes of W Maine
or[1] (ôr; *unstressed* ər) *conj.* [ME., in form a contr. of *other*, *auther*, either, but actually < OE. *oththe* (in *āther . . . oththe*, either . . . or)] a coordinating conjunction introducing an alternative; specif., *a*) introducing the second of two possibilities [beer *or* wine] *b*) introducing any of the possibilities in a series, but usually used only before the last [apples, (*or*) pears, *or* plums] *c*) introducing a synonymous word or phrase [botany, *or* the science of plants] *d*) introducing the second of two possibilities when the first is introduced by *either* or *whether* [either go *or* stay, whether to go *or* stay] *e*) substituted for *either* as the first correlative ["*or* in the heart *or* in the head"]
or[2] (ôr) *conj.*, *prep.* [ME. < OE. *ār*, var. of *ær*, *ere:* cf. ERE] [Archaic or Dial.] before; ere
or[3] (ôr) *n.* [Fr. < L. *aurum*, gold: for IE. base see EAST] *Heraldry* gold or yellow, represented in engraving by small dots powdered over a plain field
-or (ər; *occas.* ôr) 1. [ME. *-our* < OFr. *-our*, *-or*, *-eur* < L. *-or*, *-ator*] *a n.-forming suffix meaning* a person or thing that [*inventor*, *objector*] 2. [ME. *-our* < OFr. < L. *-or*] *a n.-forming suffix meaning* quality or condition [*horror*, *error*]: in Brit. usage, often **-our**
‡**o·ra** (ôr′ə) *n. pl. of* OS[2]
or·ach, or·ache (ôr′əch, är′-) *n.* [ME. *orage* < Anglo-Fr. *orache* < OFr. *arroche* < VL. **atrapica* (for L. *atriplex*) < Gr. *atraphaxys*] any of a genus (*Atriplex*) of plants of the goosefoot family, widespread in salty or alkaline areas, having usually silvery foliage and small green flowers; esp., **garden orach** (*Atriplex hortensis*), cultivated as a potherb, chiefly in France
or·a·cle (ôr′ə k'l, är′-) *n.* [ME. < OFr. < L. *oraculum*, divine announcement, oracle < *orare*, to speak, pray, beseech < *os* (gen. *oris*), the mouth: see ORAL] 1. among the ancient Greeks and Romans, *a*) the place where, or medium by which, deities were consulted *b*) the revelation or response of a medium or priest 2. *a*) any person or agency believed to be in communication with a deity *b*) any person of great knowledge or wisdom *c*) opinion or statements of any such oracle 3. the holy of holies of the ancient Jewish Temple: I Kings 6:16, 19–23
o·rac·u·lar (ô rak′yoo lər) *adj.* 1. of, or having the nature of, an oracle 2. like an oracle; wise, prophetic, mysterious, etc. —**o·rac′u·lar′i·ty** (-yə lar′ə tē) *n.* —**o·rac′u·lar·ly** *adv.*
o·rad (ôr′ad) *adv.* [< L. *os* (gen. *oris*), the mouth + -AD[2]] toward the mouth or oral region
O·ra·dea (ô räd′yä) city in NW Romania, near the Hungarian border: pop. 112,000
o·ral (ôr′əl) *adj.* [< L. *os* (gen. *oris*), the mouth < IE. base **ōus-*, mouth, edge, whence Sans. *ā́-h*, mouth, ON. *ōss*, mouth of a stream] 1. uttered by the mouth; spoken 2. of speech; using speech 3. of, at, or near the mouth 4. *Phonet.* having mouth resonance only: distinguished from NASAL 5. *Psychoanalysis* *a*) designating or of the earliest stage of psychosexual development in which interest centers around sucking, feeding, and biting *b*) designating or of such traits in the adult as friendliness, generosity, and optimism or aggressiveness and pessimism, regarded as unconscious psychic residues of that stage: cf. ANAL, GENITAL 6. *Zool.* on or of the same side as the mouth —☆*n.* an examination that is oral and not written, as in a college —**o′ral·ly** *adv.*
SYN.—**oral** refers to that which is spoken, as distinguished from that which is written or otherwise communicated [an *oral* promise, request, etc.]; **verbal**, though sometimes synonymous with **oral**, in strict discrimination refers to anything using words, either written or oral, to communicate an idea or feeling [a *verbal* image, caricature, etc.]
oral history 1. historical data consisting of personal recollections, usually in the form of a tape-recorded interview 2. the gathering and preservation of such data
o·ral·ism (ôr′əl iz′m) *n.* the theory or practice of teaching the deaf to read lips and to speak —**o′ral·ist** *adj.*, *n.*
O·ran (ō ran′; *Fr.* ô rän′) seaport in N Algeria, on the Mediterranean: pop. 430,000
o·rang (ô raŋ′, ə-) *n. same as* ORANGUTAN
Or·ange[1] (ôr′inj, är′-) ruling family of the Netherlands: see NASSAU —*adj.* of or having to do with Orangemen
Or·ange[2] (ôr′inj, är′-; *also, for 3 & 4, Fr.* ôränzh′) 1. [prob. after the *orange* groves there] city in SW Calif.: suburb of Los Angeles: pop. 92,000 2. river in South Africa, flowing from NE Lesotho west into the Atlantic: c. 1,300 mi. 3. former principality of W Europe, now in SE France 4. city in SE France: pop. 21,000
or·ange (ôr′inj, är′-) *n.* [ME. < OFr. *orenge* < Pr. *auranja* (with sp. influenced by L. *aurum*, gold & loss of initial *n* through faulty separation of art. *un*) < Sp. *naranja* < Ar. *nāranj* < Per. *nārang* < Sans. *naranga*, prob. akin to Tamil *naṟu*, fragrant] 1. a reddish-yellow, round, edible citrus fruit, with a sweet, juicy pulp 2. any of various evergreen trees (genus *Citrus*) of the rue family producing this fruit, having white, fragrant blossoms, often carried by brides, and hard, yellow wood 3. any of several plants or fruits resembling the orange 4. reddish yellow —*adj.* 1. reddish-yellow 2. made with or from orange 3. having a flavor like that of oranges —**or′ang·y** (-in jē) *adj.*
or·ange·ade (-ād′) *n.* [Fr.: see ORANGE & -ADE] a drink made of orange juice and water, usually sweetened
Orange Free State province of South Africa, west of Lesotho: formerly a Boer republic (1854–1900) & then a Brit. colony (**Orange River Colony**, 1900–10): 49,866 sq. mi.; pop. 1,387,000; cap. Bloemfontein
☆**orange hawkweed** *same as* DEVIL'S PAINTBRUSH
Or·ange·ism (ôr′inj iz′m, är′-) *n.* the principles and practices of the Orangemen
Or·ange·man (-mən) *n.*, *pl.* **-men** (-mən) [after the Prince of *Orange*, later WILLIAM III] a member of a secret Protestant society organized in N Ireland (1795)
orange pekoe a black tea of Ceylon and India: see PEKOE
or·ange·ry (ôr′inj rē, är′-) *n.*, *pl.* **-ries** [Fr. *orangerie* < *oranger*, orange tree < *orange*] a hothouse or other sheltered place for growing orange trees in cooler climates
☆**orange stick** a pointed stick, orig. of orangewood, used in manicuring

☆**no-show** (nō′shō′) *n.* [Colloq.] a person who makes a reservation, as for an airline flight, but fails to claim or cancel it

nos·ing (nō′ziŋ) *n.* [NOSE + -ING] 1. the projecting edge of a step; that part of the tread which extends beyond the riser 2. a strip, as of metal, for protecting this edge from wear 3. any projection like a stair nosing

nos·o- (nō′sō) [< Gr. *nosos*, disease] *a combining form meaning* disease *[nosology]:* also, before a vowel, **nos-**

no·sog·ra·phy (nō säg′rə fē) *n.* [prec. + -GRAPHY] the systematic description of diseases

no·sol·o·gy (nō säl′ə jē) *n.* [ModL. *nosologia:* see NOSO- & -LOGY] 1. classification of diseases 2. the branch of medicine dealing with this —**nos·o·log·ic** (näs′ə läj′ik), **nos′o·log′i·cal** *adj.* —**nos′o·log′i·cal·ly** *adv.*

nos·tal·gia (näs tal′jə, nəs-, nôs-; -jē ə) *n.* [ModL. < Gr. *nostos*, a return + -ALGIA] 1. a longing to go back to one's home, home town, or homeland; homesickness 2. a longing for something far away or long ago or for former happy circumstances —**nos·tal′gic** (-jik) *adj.* —**nos·tal′gi·cal·ly** *adv.*

nos·toc (näs′täk) *n.* [ModL., coined by Paracelsus] any of a genus (*Nostoc*) of blue-green algae, having twisted, coiled filaments embedded in a gelatinous material and forming spherical colonies

nos·tol·o·gy (näs täl′ə jē) *n.* [< Gr. *nostos*, a return + -LOGY] *earlier term for* GERONTOLOGY —**nos′to·log′ic** (-tə läj′ik) *adj.*

nos·to·ma·ni·a (näs′tə mā′nē ə, -mān′yə) *n.* [ModL. < Gr. *nostos*, a return + -MANIA] *Psychiatry* excessive or abnormal nostalgia

Nos·tra·da·mus (näs′trə dā′məs, nō′strə dä′məs) (born *Michel de Notredame*) 1503–66; Fr. astrologer

nos·tril (näs′trəl) *n.* [ME. *nosethirl* < OE. *nosthyrl* < *nos*, for *nosu*, the nose + *thyrel*, a hole < *thurh*, through: see NOSE & THROUGH] 1. either of the external openings of the nose 2. the fleshy wall on either side of the nose *[with flaring nostrils]*

nos·trum (näs′trəm) *n.* [L., neut. of *noster*, ours: ? so called from the seller's calling it "our" remedy] 1. *a)* a medicine prepared by the person selling it *b)* a patent medicine of a kind sold with exaggerated claims; quack medicine 2. a pet scheme for solving some social or political problem; panacea

nos·y (nō′zē) *adj.* **nos′i·er, nos′i·est** [NOS(E) + -Y²] [Colloq.] given to prying; inquisitive —**nos′i·ly** *adv.* —**nos′i·ness** *n.*

Nosy Parker (pär′kər) [NOSY + proper name *Parker:* reason for use uncertain] *[also* **n- p-, n- P-***]* [Colloq.] a nosy person; busybody

not (nät) *adv.* [ME. *not*, unstressed form of *noht, nought, naught:* see NOUGHT] in no manner; to no degree: a particle of negation, or word expressing the idea of *no*, often implying refusal, affirmation of the opposite, etc.: sometimes used elliptically *[whether you like it or not]*

not- (nōt) *same as* NOTO-: used before a vowel

‡**no·ta be·ne** (nō′tə bē′nē, nō′tä be′nā) [L.] note well; take particular notice

no·ta·bil·i·a (-bil′ē ə, -bil′yə) *n.pl.* [L., neut. pl. of *notabilis:* see ff.] things worthy of notice

no·ta·bil·i·ty (nōt′ə bil′ə tē) *n.* 1. *pl.* **-ties** a person who is notable or prominent 2. the quality of being notable

no·ta·ble (nōt′ə b'l; *for adj. 2, also* nät′-) *adj.* [ME. < OFr. < L. *notabilis* < *notare*, to mark, note < *nota*, a mark: see NOTE] 1. worthy of notice; remarkable; outstanding 2. [Archaic] industrious and capable, as in housekeeping —*n.* 1. a person of distinction; famous or well-known person 2. [N-] formerly in France, any of the persons of authority, rank, etc. summoned by the king as a deliberative assembly in emergencies —**no′ta·bly** *adv.*

no·tar·i·al (nō ter′ē əl) *adj.* 1. of or characteristic of a notary public 2. drawn up or executed by a notary public —**no·tar′i·al·ly** *adv.*

☆**no·ta·rize** (nōt′ə rīz′) *vt.* **-rized′, -riz′ing** to certify or attest (a document) as a notary public, esp. with a signature seal —**no′ta·ri·za′tion** *n.*

no·ta·ry (nōt′ər ē) *n., pl.* **-ries** [ME. *notarye* < OFr. *notaire* < L. *notarius* < *notare*, to NOTE] *clipped form of* NOTARY PUBLIC

notary public *pl.* **notaries public, notary publics** an official authorized to certify or attest documents, take depositions and affidavits, etc.

no·ta·tion (nō tā′shən) *n.* [L. *notatio* < *notare*, to NOTE] 1. the use of a system of signs or symbols to represent words, phrases, numbers, quantities, etc. 2. any such system of signs or symbols, as in mathematics, chemistry, music, etc. 3. a brief note jotted down, as to remind one of something, explain something, etc. 4. the act of noting something in writing —**no·ta′tion·al** *adj.*

notch (näch) *n.* [prob. by syllabic merging of ME. *an oche* < OFr. *oche, osche*, a notch < *oschier*, to notch] 1. a concave or V-shaped cut or indentation in an edge or across a surface ☆2. a narrow pass with steep sides; defile; gap 3. [Colloq.] a step; grade; degree; peg *[a notch below average]* —*vt.* 1. to cut a notch or notches in; indent with notches 2. to record or tally, as by means of notches —**notched** *adj.* —**notch′er** *n.*

note (nōt) *n.* [ME. < OFr. < L. *nota*, a mark, sign, character, letter < *notus*, pp. of *noscere*, to know < *gnoscere:* for IE. base see KNOW] 1. a mark of some quality, condition, or fact; distinguishing or characteristic feature, mood, tone, etc. *[a note of sadness]* 2. importance, distinction, or eminence *[a person of note]* 3. *a)* a brief statement of a fact, experience, etc. written down for review, as an aid to memory, or to inform someone else; memorandum *b)* [*pl.*] a record of experiences, etc. *[the notes of a journey]* 4. a comment, explanation, or elucidation, as at the foot of a page; annotation 5. notice; heed; observation *[worthy of note]* 6. any of certain types of correspondence; specif., *a)* a short, informal letter *b)* a formal diplomatic or other official communication 7. *a)* any of certain commercial papers, some of which are negotiable, relating to the owing of debts or payment of money *[a promissory note] b)* a piece of paper currency *[a Federal Reserve note]* 8. a cry or call, as of a bird 9. a signal or intimation *[a note of admonition]* 10. [Archaic or Poet.] a melody, tune, or song 11. *Music a)* a tone of definite pitch, as made by a voice or musical instrument *b)* a symbol for a tone, indicating the duration by its form and the pitch by its position on the staff *c)* a key of a piano or the like —*vt.* **not′ed, not′ing** [ME. *noten* < OFr. *noter* < L. *notare* < *nota*] 1. to pay close attention to; heed; notice; observe 2. to set down in writing; make a note of 3. to mention particularly 4. to denote, signify, or indicate 5. to set down in musical notes —**compare notes** to exchange views; discuss —**strike the right note** to say, write, or do what is specially apt or pleasing —**take notes** to write down notes, as during a lecture or interview, for later reference

NOTES
(A, whole; B, half; C, quarter; D, eighth; E, sixteenth; F, thirty-second; G, sixty-fourth)

note·book (nōt′book′) *n.* a book in which notes, or memorandums, are kept

note·case (-kās′) *n.* [Brit.] *same as* BILLFOLD

not·ed (nōt′id) *adj.* distinguished; well-known; renowned; eminent —***SYN.*** see FAMOUS —**not′ed·ly** *adv.* —**not′ed·ness** *n.*

note·less (nōt′lis) *adj.* 1. not noted; unnoticed; undistinguished 2. unmusical

note of hand *same as* PROMISSORY NOTE

note paper paper for writing notes, or letters

note·wor·thy (-wur′*th*ē) *adj.* worthy of note; deserving notice; outstanding; remarkable; notable —**note′wor′thi·ly** *adv.* —**note′wor′thi·ness** *n.*

noth·ing (nuth′iŋ) *n.* [ME. < OE. *na thing, nan thing*] 1. *a)* no thing; not anything; nought *b)* no part, element, trace, etc. *[nothing of kindness in him]* 2. *a)* nonexistence; nothingness *b)* insignificance; unimportance 3. a thing that does not exist 4. *a)* something of little or no value, seriousness, importance, etc.; triviality or trifle *b)* a person considered of no value or importance 5. a nought; zero; cipher —*adv.* not at all; in no manner or degree *[nothing daunted]* —**for nothing** 1. free; at no cost 2. in vain; uselessly 3. without reason —☆**have nothing on** to have no implicating evidence, information, etc. about —☆**in nothing flat** [Colloq.] in almost no time at all —**make nothing of** 1. to treat as of little importance 2. to fail to understand —**nothing but** only; nothing other than —**nothing doing** [Colloq.] 1. no: used as a refusal of a request 2. no result, accomplishment, etc.: an exclamation of disappointment —**nothing less than** no less than; just the same as: also **nothing short of** —**think nothing of** 1. to attach no importance to 2. to regard as easy to do

noth·ing·ness (-nis) *n.* 1. the quality or condition of being nothing or not existing; nonexistence or extinction 2. lack of value, worth, meaning, etc.; uselessness, emptiness, insignificance, etc. 3. unconsciousness or death 4. anything that is nonexistent, worthless, insignificant, useless, etc.

no·tice (nōt′is) *n.* [LME. < MFr. < L. *notitia* < *notus:* see NOTE] 1. information, announcement, or warning; esp., formal announcement or warning, as in a newspaper *[a legal notice]* 2. a brief mention or critical review of a work of art, book, play, etc. 3. a written or printed sign giving some public information, warning, or rule 4. *a)* the act of observing; attention; regard; heed; cognizance *b)* courteous attention; civility 5. a formal announcement or warning of intention to end an agreement, relation, or contract at a certain time *[to give a tenant notice]* —*vt.* **-ticed, -tic·ing** 1. *a)* to mention; refer to; comment on *b)* to review briefly 2. *a)* to regard; observe; pay attention to *b)* to be courteous or responsive to 3. [Rare] to serve with a formal notice —***SYN.*** see DISCERN —**serve notice** to give formal warning or information, as of intentions; announce —**take notice** to become aware; pay attention; observe